DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT - 9 1997

TRANSMITTED VIA FACSIMILE

Timothy R. Dring
Assistant Director, Regulatory Affairs
Novartis Consumer Health, Inc.
560 Morris Avenue
Summit, NJ 07901-1312

Re: NDA 20-076
Habitrol (Nicotine transdermal system)
MACMIS File ID #5857

Dear Mr. Dring:

This letter is in reference to Novartis Consumer Health, Inc.'s (Novartis) submission of promotional materials under cover of Form FDA 2253 for Habitrol (nicotine transdermal system) consisting of a journal advertisement (HAB 70229). The Division of Drug Marketing, Advertising, and Communications (DDMAC) regards this journal advertisement to be false and/or misleading under the Federal Food, Drug, and Cosmetic Act and regulations promulgated thereunder.

Specifically, DDMAC is concerned that the presentation of the information in this advertisement creates an impression that the use of Habitrol results in quit rates of over 50 percent of smokers. However, the fine print at the bottom of the page presents the data that the 52% figure was derived from and it states that the quit rate improved from 7.9% to 12% with a physician's intervention. First, without combining the statement concerning the increase in quit rates as a result of a physician's intervention with the actual quit rates themselves is misleading, in that it does not provide an accurate representation of the efficacy of the nicotine transdermal system.

Second, the claim that a physician's involvement improves quit rates by 52% is not solely based on studies that used the nicotine transdermal system. Thus, to suggest that physician intervention would increase the quit rate for the nicotine transdermal system by such a large amount is false or misleading.

In addition, this advertisement fails to present information relating to side effects and contraindications with a prominence and readability reasonably comparable with the presentation of information relating to the effectiveness of the drug. Thus, DDMAC considers this advertisement to lacking in fair balance or otherwise misleading.

Novartis should immediately suspend all promotional activities and materials that convey or contain the allegedly violative claims or information identified in this letter. Novartis should submit a written response to DDMAC on or before October ??, 1997, describing the steps taken to ensure that the use of these materials have been discontinued.

Novartis should address its correspondence and any additional questions to the undersigned at the Division of Drug Marketing, Advertising, and Communications, HFD-40, Rm 17 B-17, 5600 Fishers Lane, Rockville, Maryland 20857. DDMAC reminds Novartis that only written communications are considered official. In all future correspondence regarding this matter, please refer to MACMIS ID #5857, in addition to the NDA number.

Sincerely,

Stephen W. Sherman
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications